DEPARTMENT OF HEALTH & HUMAN SERVICES
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Medicare Prescription Drug Data Strategy:
Improving Evidence for Patient Care
Through the Medicare Prescription Drug Benefit

The Medicare Modernization Act (MMA) provides new opportunities not only to ensure that seniors and people with disabilities receive up-to-date care involving prescription drugs, but also to help people with Medicare get the most benefits at the lowest cost from this coverage. By implementing the drug benefit though prescription drug plans (PDPs) that offer new tools based on health information technology, such as e-prescribing programs and other electronic systems, people with Medicare and their doctors will have new support for using medicines effectively. These electronic systems will also help provide better evidence on the experience of people with Medicare in using medications, including better information on unusual adverse events and on the impact of drugs on avoiding disease complications and their associated medical costs. With better evidence, doctors and patients can get greater benefits from Medicare drug coverage, while reducing the overall costs of health care.

Until now, the medical evidence available on the effects of prescription drugs for particular kinds of Medicare beneficiaries in actual practice has had important limitations. For example, when a drug is approved it is often not known how the drug will work in patients different from those studied for the FDA-approved indications, such as elderly patients with complex combinations of diseases or people with poor kidney function, or other patients for whom important benefits from the drug are suspected but have not been demonstrated. In addition to providing help with drug costs for such beneficiaries, the electronic information on prescription drug use developed with the drug benefit[1] provides new opportunities to learn about drug utilization patterns and the adverse events, avoidance of disease complications, and consequences for other Medicare costs that are associated with different ways that drugs might be used by Medicare beneficiaries.

If such data are used carefully, with due attention to their limitations as well as the opportunities they provide, this information could add to the extensive evidence that is developed through existing prospective research studies, including randomized controlled trials, registries, and other clinical studies. To generate new evidence to improve quality

[1] Instructions: Requirements For Submitting Prescription Drug Event Data April 12, 2005. http://www.cms.hhs.gov/pdps/FINALPAPER041205.pdf

of care, CMS intends to support a public-private partnership to learn more about key issues involving prescription drug use and health outcomes for Medicare beneficiaries. The electronic data developed in the Medicare drug benefit will provide a foundation for this evidence. Using strict procedures that meet HIPAA privacy and security protections, evidence on important questions on the use, risks, and benefits of certain drug therapies can be developed by linking relevant Part D data to hospital, physician, and other medical utilization data (Medicare Part A and B data). Similar data linkages are already performed under confidential conditions by Medicare's Quality Improvement Organizations for other types of data for evidence development, for example, studies involving medical devices and procedures. Such data would be "de-identified" when they are used in evaluations to develop better evidence.

The primary use of the de-identified Part D data, combined with Medicare Part A/B data, will be to provide better evidence on the consequences of drug therapy choices, including their association with important outcomes such as hospitalization with specific complications, death, and overall Medicare costs. This evidence will be used by beneficiaries and their health professionals to make better informed decisions about their treatments.

The types of evidence that could be developed with these data include:

- Collaborative efforts for improved post-market surveillance of FDA-approved drugs and devices. In addition to relying on spontaneous reporting of adverse events by busy health professionals, questions about the association of drug use and serious adverse events could be answered using routine systems, with much larger patient populations. Through collaboration with product developers, these data could potentially augment "Phase 4" evaluations of approved drugs, which today often require setting up a new data collection and monitoring system rather than relying on routine systems like those that will be available with the Part D benefit.

- More evidence about drug use in a broader range of conditions, including more detailed evidence on particular types of patients. This includes off-label uses where limited evidence may exist now, and the use of treatments in circumstances different from those evaluated in available studies. Evidence could be developed on the longer-term patterns of health outcomes and overall medical costs associated with long-term use of different drug treatments, and with large numbers of patients with particular characteristics. For example, certain drug combinations may be associated with different consequences for particular kinds of patients with chronic illnesses, and evidence on these differences developed from the Medicare drug benefit could support the evaluation and improvement of best practices. These types of questions are often not feasible to study in pre-market clinical trials, and are difficult to study in a post-market setting without the kinds of data that will be developed on the Medicare benefit. Evidence could also be developed on the effect of formularies and other features of drug coverage and beneficiary support programs on the outcomes and overall costs of care. In

addition, new methods could be developed to determine which combinations of drugs are most effective in specific target populations with specific disease burdens.

Private health plans and other plans working with PBMs also have electronic data on drug use, health outcomes, and costs similar to that used by Medicare to administer the Medicare drug benefit. Such data on beneficiaries in Medicare Advantage and on Americans under age 65 could complement Medicare claims data, particularly for products used by patients of multiple ages. A public-private collaboration using consistent electronic data from across these different patient populations, again using de-identified data so that no confidential patient information would be used, could provide more comprehensive evidence than could be obtained from the experience of traditional Medicare beneficiaries alone. This would require collaborative steps to promote consistent data collection and analysis. CMS is supporting analogous steps now for consistent, reliable, and efficient reporting on clinically valid quality measures, for example in the Hospital Quality Alliance and the Ambulatory Care Quality Alliance.

While CMS can provide useful de-identified data, effective evidence development will require public-private collaboration in critical areas. First, in order for electronic data from Medicare and other health plans to provide the greatest value for developing better evidence, expert involvement is essential to identify top priorities and methods for evidence development. There are a number of possible sources for independent expert guidance for this process. For example, under Section 1013 in MMA, the Agency for Healthcare Research and Quality (AHRQ) is charged with identifying priorities for studies to improve the effectiveness of Medicare and Medicaid by disease area and condition. The Food and Drug Administration (FDA) has public advisory committees that identify and address information gaps related to the safety of specific drugs. The Institute of Medicine could also provide guidance on evidence development by convening experts and other stakeholders. Medical expert groups, including existing networks of researchers in cancer care, heart disease care, and many other areas, could provide guidance. Specific areas for drug evaluations could also be identified or developed through a public input process.

Second, some limited support would be required for independent expert analyses to reach conclusions based on the data on drugs, medical outcomes, and overall costs. For example, the Centers for Education and Research on Therapeutics (CERTs) or other publicly or privately funded investigators or research networks could evaluate the data, possibly in conjunction with other sources of evidence. With the systematic development of consistent data, such studies would be relatively inexpensive to conduct.

As we implement electronic data systems to support the drug benefit, CMS intends to consult with other private and public entities about the best approaches by which data might be developed, validated, and reported to support these types of projects. Over the next several months, CMS will seek input from interested stakeholders through a variety of mechanisms, including an upcoming open door meeting to discuss the technical, policy, and practical issues involved with this effort.